

**SAMBUCOL COLD AND FLU NIGHT TIME SYRUP- byronia, chamomilla, gelsemium sempervirens, passiflora incarnata, sambucus nigra, silicea, sulphur, zincum gluconicum, water liquid
PharmaCare US, Inc.**

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

DRUG FACTS:

ACTIVE INGREDIENTS:

Bryonia 6X, Chamomilla 6X, Gelsemium Sempervirens 6X, 12X, 30X, Passiflora Incarnata 6X, Sambucus Nigra 4X, 6X, Silicea 12X, Sulphur 12X, Zincum Gluconicum 3X, Water USP QS.

INDICATIONS:

Temporarily relieves the symptoms of cold and flue while providing a restful night's sleep.

Fast temporary relief from

- Sinus congestion
- Cough
- Aches & pains
- Fever & chills
- Sore throat
- Sleeplessness
- Headache

WARNINGS:

Sore Throat Warning - Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea and vomiting may be serious. Consult a physician promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by a physician.

Stop use and ask a doctor if: - Symptoms worsen - Any new symptoms appear - Fever last for more than three days - Respiratory symptoms persist for more than seven days.

If pregnant or breast feeding: ask a health care professional before using.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

-Do not use if bottle seal is broken.

KEEP OUT OF REACH OF CHILDREN:

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

-For best results use at the first sign of symptoms of a cold or flu and continue to use for an additional 48 hours after symptoms subside.

-Adults and children 4 years of age and older: Take 1 serving (10 ml) at the onset of symptoms.

-Repeat every three hours until symptoms are gone.

-Children under 4 years of age: Consult a doctor before use.

INDICATIONS:

Samucol Cold & Flu Night-Time Relief:

- Safe for the whole family*
- No known drug interactions
- No known side effects
- Pleasant berry taste
- Fast temporary relief from cold & flu symptoms
- Provides a restful night's sleep
- With natural elderberry & zinc
- Unique homeopathic formulation
- Great tasting syrup
- Soothing to the throat
- Non-habit forming

*Children under 4: Consult a doctor before use.

INACTIVE INGREDIENTS:


Citric Acid, Elderberry Natural Flavor, European Elder (*Sambucus nigra*) Extract, Fructose, Glycerin, Purified Water, Sodium Benzoate, Sorbitol, Xanthan Gum, Zinc Gluconate.

QUESTIONS:

Sambucol is a registered trademark of
PharmaCare Laboratories Pty Ltd.
Manufactured for and distributed by
PharmaCare U.S. Inc.
San Diego, CA 92108
Questions? Comments?
Visit our website
www.SambucolUSA.com
or call 1-888-871-9098

PACKAGE DISPLAY LABEL:

Sambucol
Black Elderberry
COLD & FLU
NIGHT-TIME SYRUP
HOMEOPATHIC
4 Fl oz (120 mL)

Sambucol® BLACK ELDERBERRY COLD & FLU		Sambucol® BLACK ELDERBERRY COLD & FLU		Sambucol® BLACK ELDERBERRY COLD & FLU		Sambucol® BLACK ELDERBERRY COLD & FLU	
Drug Facts Active Ingredients (in each serving) Bryonia 6X HPUS Chamomilla 6X HPUS Gelsemium sempervirens 6X 12X 30X HPUS Plasilifera incarnata 6X HPUS Sambucus nigra 4X 6X HPUS Silica 12X HPUS Sulphur 12X HPUS Zincum gluconicum 3X HPUS Purpose Fever with chills, head congestion, stiffness, headache Congestion, fever & chills, headache, sore throat Gelsemium sempervirens 6X 12X 30X HPUS: Fever with chills, aches, head congestion Plasilifera incarnata 6X HPUS: Sleeplessness, restlessness with fever Sambucus nigra 4X 6X HPUS: Nasal congestion, cough, fever Silica 12X HPUS: Nasal congestion, cough, fever, sleeplessness Sulphur 12X HPUS: Colds, fever, head & chest congestion, sore throat Zincum gluconicum 3X HPUS: Sore throat, runny nose The letters "HPUS" indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States.		(Drug Facts cont.) Warnings Sore Throat Warning – Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea and vomiting may be serious. Consult physician promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by a physician. Stop use and ask a doctor if: • Symptoms worsen. • Any new symptoms appear. • Fever lasts for more than three days. • Respiratory symptoms persist for more than seven days. • If pregnant or breast feeding: ask a health care professional before using. Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. • Do not use if bottle seal is broken. Directions • For best results, use at the first sign of symptoms of a cold or flu and continue to use for an additional 48 hours after symptoms subside. • Adults and children 4 years of age and older: Take 1 serving (10ml) at the onset of symptoms. • Repeat every three hours until symptoms are gone. • Children under 4 years of age: Consult a doctor before use. Other information Active ingredients are monographed and microdiluted in accordance with the Homeopathic Pharmacopoeia of the United States and are non-toxic and have no known side effects. Inactive Ingredients Citric acid, elderberry natural flavor, European elder (Sambucus nigra) berry extracts, fructose, glycerin, purified water, sodium benzoate, sorbitol, xanthan gum, zinc gluconate.		NIGHT-TIME SYRUP  Temporarily relieves the symptoms of cold and flu while providing a restful night's sleep Fast temporary relief from: • Sinus congestion • Cough • Aches & pains • Fever & chills • Sore throat • Sleeplessness • Headache 4 Fl oz 120mL HOMEOPATHIC		Sambucol® Cold & Flu Night-Time Relief: • Safe for the whole family* • No known drug interactions • No known side effects • Pleasant berry taste • Fast temporary relief from cold & flu symptoms • Provides a restful night's sleep • With natural elderberry & zinc • Unique homeopathic formulation • Great tasting syrup • Soothing to the throat • Non-habit forming *Children under 4: Consult a doctor before use. Sambucol® is a registered trademark of PharmaCare Laboratories Pty Ltd. Manufactured for and distributed by PharmaCare U.S. Inc. San Diego, CA 92108 Questions? Comments? Visit our website www.SambucolUSA.com or call 1-888-871-9098 HOMEOPATHIC	

SAMBUCOL COLD AND FLU NIGHT TIME SYRUP

byronia, chamomilla, gelsemium sempervirens, passiflora incarnata, sambucus nigra, silicea, sulphur, zincum gluconicum, water liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52053-0002
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	6 [hp_X] in 1 mL
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA RECUTITA	6 [hp_X] in 1 mL
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	6 [hp_X] in 1 mL
PASSIFLORA INCARNATA FLOWERING TOP (UNII: CLF5YFS11O) (PASSIFLORA INCARNATA FLOWERING TOP - UNII:CLF5YFS11O)	PASSIFLORA INCARNATA FLOWERING TOP	6 [hp_X] in 1 mL
SAMBUCUS NIGRA FLOWERING TOP (UNII: CT03BSA18U) (SAMBUCUS NIGRA FLOWERING TOP - UNII:CT03BSA18U)	SAMBUCUS NIGRA FLOWERING TOP	4 [hp_X] in 1 mL
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	12 [hp_X] in 1 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	12 [hp_X] in 1 mL
ZINC GLUCONATE (UNII: U6WSN5SQ1Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC GLUCONATE	3 [hp_X] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EUROPEAN ELDERBERRY JUICE (UNII: Z4IFJ0AK1E)	
FRUCTOSE (UNII: 6YSS42VSEV)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52053-0002-2	1 in 1 CARTON	09/06/2013	02/19/2022
1	NDC:52053-0002-1	120 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/06/2013	02/19/2022

Labeler - PharmaCare US, Inc. (026889965)

Registrant - Apotheca Company (844330915)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Company		844330915	manufacture(52053-0002) , api manufacture(52053-0002) , label(52053-0002) , pack(52053-0002)

Revised: 11/2021

PharmaCare US, Inc.